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Glenn P. Ladwig, Patent Attorney

INFORMATION DISCLOSURE STATEMENT Examining Group 1634 Patent Application Docket No. USF-211XT Serial No. 10/605,452

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit

1634

Applicants

William G. Kerr, John M. Ninos

Serial No.

10/605,452

Filed

September 30, 2003

Conf. No.

2451

For

Novel SH2containing Inositol 5'-phosphatase Isoform That Partners With The

Grb2 Adapter Protein

MS AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, the applicants have not submitted copies of the U.S. patents or published U.S. applications cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii).

This information is being submitted subsequent to the later of three months after the filing date of the present application or the mailing of the first Office Action on the merits, but before the mailing of a final action or the notice of allowance. Please charge the fee of \$180.00 to Deposit Account No. 19-0065.

The applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statements.

Respectfully submitted,

Glenn P. Ladwig
Patent Attorney

Registration No. 46,853

Phone No.: 352-375-8100 Fax No.: 352-372-5800 Address: P.O. Box 142950

Gainesville, FL 32614-2950

GPL/mv

Attachments: Form PTO/SB/08 (6 pages); copies of some references cited therein.



PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for for	m 1449A/PTO			Con	mplete if Known
INFORMATION DISCLOSURE		Application Number	10/605,452		
 				Filing Date	September 30, 2003
STATEMENT BY APPLICANT	First Named Inventor	William G. Kerr			
(u	se as many sheets a	as ned	essary)	Art Unit	1634
				Examiner Name	Joanne Hama
Sheet	1	of	6	Attorney Docket Number	USF-211XT

			U.S. PATENT DO	OCUMENTS	
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-10/709,801	05-28-2004	Desponts et al.	All
	U2	US-10/904,667	11-22-2004	Kerr et al.	All
	U3	US-2002/0137711 A1	09-26-2002	Kerr	All
	U4	US-2002/0165192 A1	11-07-2002	Kerr et al.	All
	U5	US-2004/0072298 A1	04-15-2003	Sauvageau et al.	All
	U6	US-4,603,112	07-29-1986	Paoletti et al.	All
	U7	US-4,769,330	09-06-1988	Paoletti et al.	All
	U8	US-4,777,127	10-11-1988	Suni et al.	All
	U9	US-5,017,487	05-21-1991	Stunnenberg et al.	All

		FOREIGN	PATENT DOCU	JMENTS		_
		Foreign Patent Document	Buttle die e Bete		Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	F1	WO 89/01973 A2	03-09-1989	Applied Biotech. Inc.	All	
	F2	WO 91/02805 A2	03-07-1991	Viagene, Inc.	All	
	F3	WO 92/06693 A1	04-30-1992	Fox Chase Cancer Ctr.	All	
	F4	WO 97/10252 A1	03-20-1997	Fred Hutchinson Cancer Research	All	
	F5	WO 97/12039 A2	04-03-1997	Krystal	All	
<u> </u>	F6	EP 0 345 242 A2	12-06-1989	Smithkline Biologicals	All	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP901.04. Enter Office that issued the document, by the two-letter code (MPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under MPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary)  Art Unit  Examiner Name	Con	Complete if Known				
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	10/605,452			
			Filing Date	September 30, 2003		
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	(use	as many sheets	as ned	cessary)	Art Unit	1634
					Examiner Name	Joanne Hama
Sheet		2	of	6	Attorney Docket Number	USF-211XT

			U.S. PATENT DO	OCUMENTS	
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U10	US-5,166,057	11-24-1992	Palese et al.	All
	U11	US-6,025,198	02-15-2000	Bennett et al.	All
	U12	US-6,090,621	07-18-2000	Kavanaugh et al.	All
	U13	US-6,703,215	03-09-2004	Erneux	All
	U14	US-			
	U15	US-			
	U16	US-			
	U17	US-			
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Examiner Initials*	Cite No. <sup>1</sup>	Country Code 3 - Number 4 - Kind Code5 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	F7	EP 0 440 219 A1	08-07-1991	Schwiz, Serum- & Impfinstitut Bern	All	
	F8	GB 2 200 651	08-10-1988	Khalaf Al-Sumidale	All	
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	F12					

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Complete if Known

Application Number 10/605,452

Filing Date September 30, 2003

First Named Inventor William G. Kerr

Group Art Unit 1634

Examiner Name Joanne Hama

## Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 6 Attorney Docket Number USF-211XT

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R1	AGRAWAL, S. "Antisense oligonucleotides: towards clinical trials" <i>TIBTECH</i> , 1996, 14:376-387.	
	R2	AGRAWAL, S. and KANDIMALLA, E. "Antisense therapeutics: is it as simple as complementary base recognition?" <i>Molecular Med. Today</i> , 2000, 6:72-81.	
	R3	AKAGI, K. et al. "Cre-mediated somatic site-specific recombination in mice" Nucleic Acids Res, 1997, 25(9):1766-1773.	
	R4	BENDER, M.A. et al. "Description and targeted deletion of 5' hypersensitive site 5 and 6 of the mouse β-globin locus control region" <i>Blood</i> , 1998, 92:4394-4403.	
	R5	BRAASCH, D.A. and COREY, D.R. "Novel antisense and peptide nucleic acid strategies for controlling gene expression" <i>Biochemistry</i> , 2002, 41(14):4503-4510.	
	R6	BRANCH, A. "A good antisense molecule is hard to find" <i>Trends in Biochem.</i> , 1998, 23:45-50.	
	<b>R</b> 7	CANTLEY, L.C. et al. "Oncogenes and signal transduction" Cell, 1991, 64:281-302.	
	R8	CHIRILA, T. et al. "The use of synthetic polymers for delivery of therapeutic antisense oligodeoxynucleotides" Biomaterials, 2002, 23:321-342.	
	R9	CROOKE, S.T. "Basic principles of antisense therapeutics" in Antisense Res. and Application, chapter 1, pgs 1-50, S. Crooke, Ed., Springer-Verlag, 1999.	
	R10	DESPONTS, C. et al. "MHC class I inhibitory receptors on natural killer cells recruit SHIP in an attempt to control cell survival" FASEB Journal, March 20, 2002, 16(4):A706, abstract.	
	R11	EVANS, D.J. et al. "An engineered poliovirus chimaera elicits broadly reactive HIV-1 neutralizing antibodies" Nature, 1989, 339:385-388.	
	R12	FISHER-HOCH, S.P. et al. "Protection of rhesus monkeys from fatal Lassa fever by vaccination with recombinant vaccinia virus containing the Lassa virus glycoprotein gene" PNAS, 1989, 86:317-321.	
	R13	GEWIRTZ, A.M. et al. "Facilitating oligonucleotide delivery: Helping antisense deliver on its promise" <i>Proc. Natl. Acad. Sci. USA</i> , 1996, 93:3161-3163.	

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Signature	Considered

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First Named Inventor	William G. Kerr	
Group Art Unit	1634	
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Attorney Docket Number	USF-211XT	

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	R14	GHANSAH, T. et al. "A role for the SH2-containing inositol phosphatase in the biology of natural killer cells and stem cells" Activating and Inhibitory Immunoglobulin-like Receptors, 2001, pp. 129-140.	
<del></del>	R15	GHANSAH, T. et al. "Target disruption of Src homology 2-containing 5' inositol phosphatase (SHIP) alters PI3K/AKT and MAPK signal transduction pathways in murine natural killer cells" FASEB Journal, March 20, 2002, 16(4):A706, abstract.	
	R16	GHANSAH, T. et al. "The Src homology 2 containing inositol phosphatase is vital for the function and homeostatis of Natural Killer cells" FASEB Journal, March 7, 2001, 15(4):A655, abstract.	
	R17	GUZMAN, R.J. et al. "Molecular and cellular cardiology/receptors: efficient and selective adenovirus-mediated gene transfer into vascular neointima" Circulation, 1993, 88(6):2838-2848.	
	R18	HAWKINS, P.T. et al. "Platelet-derived growth factor stimulates synthesis of PtdIns(3,4,5)P <sub>3</sub> by activating a PtdIns(4,5)P <sub>2</sub> 3-OH kinase" <i>Nature</i> , 1992, 358:157-910.	
	R19	HELD, W. et al. "Transgenic expression of the Ly49A natural killer cell receptor confers class I major histocompatibility complex (MHC)-specific inhibition and prevents bone marrow allograft rejection" J. Exp. Med., 1996, 184(5):2037-2041.	
	R20	HELGASON, C.D. et al. "Homeostasis and regeneration of the hematopoietic stem cell pool are altered in SHIP-deficient mice" Blood, 2003, 102(10):3541-3547.	
	R21	HUBER, M. et al. "The src homology 2-containing inositol phosphatase (SHIP) is the gatekeeper of mast cell degranulation" <i>Proc. Natl. Acad. Sci. USA</i> , 1998, 95(19):11330-11335.	
	R22	JEFFERSON, A.B. et al. "Properties of type II inositol polyphosphate 5-phosphatase" J. Biol. Chem., 1995, 270(16):9370-9377.	
***	R23	JOLLY, D. et al. "Viral vector systems for gene therapy" Cancer Gene Therapy, 1998, 1(1):51-64.	
	R24	KASS-EISLER, A. et al. "Quantitative determination of adenovirus-mediated gene delivery to rat cardiac myocytes in vitro and in vivo" PNAS, 1993, 90:11498-11502.	
	R25	KERR, WILLIAM G. et al., Critical Role for SHIP in engraftment of histo-incompatible stem cells, Oncology Research, 2001, 12:285.	
	R26	KLIPPEL, A. et al. "Membrane localization of phosphatidylinositol 3-kinase is sufficient to activate multiple signal-transducing kinase pathways" <i>Mol. Cell. Biol.</i> , 1996, 16(8):4117-4127.	-

Examiner	Date	]
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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10/605,452 **Application Number** September 30, 2003 **Filing Date** William G. Kerr First Named Inventor **Group Art Unit** 1634 **Examiner Name** Joanne Hama

**Attorney Docket Number** USF-211XT of 6 Sheet

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	R27	KOH, C. et al. "Augmentation of antitumor effects by NK cell inhibitory receptor blockade in vitro and in vivo" Blood, 2001, 97(10):3132-3137.		
	R28	KOLLS, J. et al. "Prolonged and effective blockade of tumor necrosis factor activity through adenovirus-mediated gene transfer" PNAS, 1994, 91:215-219.		
	R29	LANIER, L.L. "NK cell receptors" Annual Rev of Immunology, 1998, 16:359-393.		
	R30	LIU, Q. et al. "SHIP is a negative regulator of growth factor receptor-mediated PKB/Akt activation any myeloid cell-survival" Genes & Dev., 1999, 13(7):786-791.		
	R31	LIU, Q. et al. "The inositol polyphosphate 5-phosphatase SHIP is a crucial negative regulator of B cell antigen receptor signaling" J. Exp. Med., 1998, 188(7):1333-1342.		
	R32	LOTZOVA, E. et al. "Prevention of Rejection of Allogeneic Bone Marrow Transplants by NK-1.1 Anti Serum" Transplantation, 1983, 35(5):490-494.		
	R33	LUCAS, D.M. and ROHRSCHNEIDER, L. "A novel spliced form of SH2-containing inositol phosphatase is expressed during myeloid development" <i>Blood</i> , 1999, 93(6):1922-1933		
	R34	MOODY, J.L. et al. "Anemia, thrombocytopenia, leukocytosis, extramedullary hematopoiesis, and impaired progenitor function in Pten*/-SHIP*- mice: a novel model of myelodysplasia" <i>Blood</i> , 2004, 103:4503-4510.		
	R35	OVERBAUGH, J. et al. "Molecular cloning of a feline leukemia virus that induces fatal immunodeficiency disease in cats" <i>Science</i> , 1988, 239:906-910.		
	R36	PALU, G. et al. "In pursuit of new developments for gene therapy of human diseases" J. Biotech, 1999, 68:1-13.		
	R37	PIHL-CAREY, K. "Disease drug fails in phase III" BioWorld Today, 1999, 10:1-2.		
	R38	POZNANSKY, M. et al. "Gene transfer into human lymphocytes by a defective human immunodeficiency virus type 1 vector" J. Virol., 1991, 65:532-536.		
	R39	RUGGERI, L. et al. "Role of natural killer cell alloreactivityin HLA-mismatched hematopoietic stem cell transplantation" Blood, 1999, 94(1):333-339.		

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Sheet	6	of	6	Attorney Docket Number	USF-211XT

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	item (book magazine journal serial symposium catalog etc.) gate page(s) volume-issue			
	R40	SABIN, A.B. and BOULGER, L.R. "History of Sabin attenuated poliovirus oral live vaccine strains" <i>J. of Biol. Standardization</i> , 1973, 1:115-118.		
	R41	SAMULSKI, R.J. et al. "Helper-free stocks of recombinant adeno-associated viruses: normal integration does not require viral gene expression" J. Vir., 1989, 63(9):3822-3828.		
	R42	STEPHENS, L.R. et al. "Agonist-stimulated synthesis of phosphatidylinositol(3,4,5)-trisphosphate: a new intracellular signaling system?" <i>Biochim. Biophys Acta</i> , 1993, 1179:27-75.		
	R43	TAMM, I. et al. "Antisense therapy in oncology: new hope for an old idea?" The Lancet, 2001, 358:489-497.		
	R44	TU, Z. et al. "Embryonic and hematopoietic stem cells express a novel SH2-containing inositol 5'-phosphatase isoform" <i>Blood</i> , October 2001, 98(7):2028-2038, available online September 21, 2001.		
	R45	WANG, C.Y. and HUANG, L. "pH-sensitive immunoliposomes mediate target-cell-specific delivery and controlled expression of a foreign gene in mouse" <i>PNAS</i> , 1987, 84:7851-7855.		
	R46	WANG, J-W. et al. "Influence of ZSHIP on the NK Repertoire and Allogeneic Bone Marrow Transplantation" Science, 2002, 295(5562):2094-2097.		
	R47	WOLF, 1 et al. "Cloning of the genomic locus of mouse SH2 containing inositol 5-phosphatase (SHIP) and a novel 110-kDa splice isoform, SHIP6" Genomics, 2000, 69(1):104-112.		
	R48	YOKOYAMA, W.M. "Natural killer cell receptors" Current Opin in Immunology, 1998, 10(3):298-305.		
	R49			
	R50			
	R51		<u> </u>	
	R52			

Examiner	Date	
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